

Explanation for entries in Column E of USDA form

Customer # 1345

Registration # 93-R-0381

Species: Guinea Pig

Number:388

Explanation per CFR 9, 2.36 b (7)

Animals were used to screen novel therapeutics for potential activity as a human therapeutic for various respiratory distress disorders, primarily asthma. Experimental protocol resulted in some animals (especially untreated controls) experiencing short-term respiratory distress characterized by airway spasm. Although bronchoconstriction of this type is not characterized by human asthmatics as a painful experience, it may cause anxiety and distress. Therefore, animals may also experience distress related to this short term experimentally induced compromise. Drug intervention (beyond the testing paradigm) to eliminate distress was contraindicated due to the scientific need to test the novel compounds in the disease model.

Note: No exceptions to the regulations and standards were requested by the PI or approved by the IACUC.

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Hapion Control no 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
74-F-0001

CUSTOMER NO.
1433

FORM APPROVED
OMD NO. 0579-0038

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

AIR FORCE RESEARCH LAB
2509 KENNEDY CR
VETERINARY SCIENCES DIVISION
BROOKS AF BASE, TX 78235-511

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS(s)

AIR FORCE RESEARCH LAB
BROOKS AF BASE, TX 78235

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs				16	16
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits		3	6		9
9. Non-Human Primates	10	15	89	5	110
10. Sheep					
11. Pigs			187		187
12. Other Farm Animals					
13. Other Animals					
Mice			409	685	1094
Rats		31	383	202	616
Frogs			26		26

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

11/18/2004

Interagency Report Control No
0180-004-AN

FORM APPROVED
OMB NO. 0572-0038

AIR FORCE RESEARCH LAB
2608 KENNEDY CR
VETERINARY SCIENCES DIVISION
BROOKS AF BASE, TX 78235-611

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and if any required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

DATE SIGNED

11/18/2004

APHIS Form 7023 Column E Explanation

This form is intended as an aid to completing the APHIS Form 7023 Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number:

74-F-0001

2/3. Species (common name) & Number of animals used in this study:

Dogs (15)

4. Explain the procedure producing pain and/or distress.

Dogs will be exposed to a non-lethal weapon systems (b)(2) which penetrates the skin of its target to a depth of approximately 0.3 mm, leading to intense, momentary pain and escape/fight behavior.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

The question that this proposed research is designed to answer is: □What is the effect of a specific form of momentary and escapable pain on the behavior of a dog, specifically a military working dog.□ More specifically, the key question is: □does this type of pain impact in the short □ or long-term the MWD's trained behavior?□ In order to answer these questions, an awake, alert, and unaffected (by use of analgesics, tranquilizers, etc) dog must be used. This is a study in which the use of anesthetics and/or analgesics would be contraindicated.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency: None.

CFR:

APHIS Form 7023 Column E Explanation

This form is intended as an aid to completing the APHIS Form 7023 Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 74-F-0001

2/3. Species (common name) & Number of animals used in this study:

Non-Human Primates (5)

4. Explain the procedure producing pain and/or distress.

Monkeys are required to perform a continuous compensatory tracking task, on the primate equilibrium platform (PEP). By the nature of this aversively motivated task performance, the subject must avoid or escape the aversive stimulus (mild tail shock) by meeting the performance requirements of the task.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

The criterion for shock delivery is set so that trained animals can easily perform for many hours without experiencing a shock. Many animals voluntarily experience an occasional shock to "test the system" i.e., to ascertain whether they are still being required to perform. This demonstrates the necessity of maintaining the shock contingency and the mildness of the distress involved. Attempts to train similar performance under appetite motivation (food reward) for successful performance are counterproductive. Such training has been attempted and was found to take at least 4 to 10 times longer to produce a final performance that is much less stable than that attained by aversively motivated subjects.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency: None.

CFR:

1. Registration Number: 74-F-0001 / 1433

2/3. Species (common name) & Number of animals used in this study:

Mice (685)

4. Explain the procedure producing pain and/or distress.

Mice will be infected with (b)(2) will be delivered to the lungs by placing drops of spore suspension on the tip of the nose and allowing inhalation while under anesthesia. Resulting infection can produce pain/distress.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

The use of analgesics is not justified since this may be a confounder in the progress of infection.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency: None.

CFR:

Approval Status:

Approved/Disapproved By:

Date:

Disapproved Reason:

1. Registration Number: 74-F-0001 / 1433

2/3. Species (common name) & Number of animals used in this study:

Rats (202)

4. Explain the procedure producing pain and/or distress.

1. Rats will be exposed to millimeter waves, environmental heat, and infrared heating. They may experience pain during the recovery period but will not be given routine analgesia. 2. Rats will be given kainic acid injections as a necessary positive control for neuronal damage.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below)

1. Routine administration of analgesia to the recovery animals will not be used because pain and distress is expected to be minimal and the analgesic is very likely to confound the results of the assays used in this study. Animals that are identified as moribund or in noticeable pain or distress will be immediately and humanely euthanized. 2. The use of kainic acid to induce neurodegeneration leads to seizures. While the kainic acid seizures are not painful, there may be some distress associated with the prodromal period associated with an oncoming seizure. Induction of neurodegeneration is necessary to the protocol. Because of the nature of the system being studied, some pain and discomfort are unavoidable.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency: None.

CFR:

Approval Status:

Approved/Disapproved By:

Date:

Disapproved Reason: